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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,089	10/16/2000	Hans J. Hansen	18733/1002	2717

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EXAMINER	
HUFF, SHEELA JITENDRA	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/688,089	HANSEN, HANS J.	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,49,51-53,55,58 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,49,51-53,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 48-49, 51-53 and 55 and 58-59 are pending.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48-49, 51-53 and 55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Eshhar et al PNAS vol. 90 p. 720 (1/1993), WO 92/15322, Wagner et al, Biotechnology Therapeutics vol. 3 p. 81 (1992) and applicant's admission on page 22(lines 10-24) and further in view of Hansen et al, Cancer vol. 71 p. 2478 (1993).

Please note: Losman has removed from the rejection and claims 58-59 have also been removed from the rejection. The rejection reads as follows:

Eshhar et al disclose the construction and use of chimeric genes comprised of a single-chain Fv domain of an antibody linked to the T cell receptor (TCR) or CD3, which is the principal triggering receptor complex of T cells(p. 720-second column-second full paragraph). The mechanism of action of the gene, includes being expressed in T cells, and when encountering the antigen, the complex emits signals for T cell activation, which results in the secretion of lymphokines and target cell lysis. (p. 720-second column-top). This reference also discloses the use of such chimeric genes in adoptive immunotherapy(p. 720-first column, first paragraph after the abstract).

The only difference between the instant invention and the reference is a specific showing that the chimeric gene can use used in adoptive immunotherapy, a specific showing that the immunoglobulin used can recognize a TAA or a disease caused by an infectious agent and the use of cytokines and/or the administration of an anti-ID and the specific use of CEA.

The WO shows that such chimeric genes can be used in adoptive immunotherapies where the disease is either a tumor or an infectious state(p. 29 and p. 1).

On page 22 of the specification, applicant admits that it is routine in the art to administer cytokines in immunotherapy to further the immune response.

Wagner et al teach the approach of tumor immunotherapy by the activation of the idiotypic network. This approach uses both Ab1 and Ab2 antiboides and produce an

Ab2β which mimics the TAA. Thus, this reference not only shows that antibodies directed against TAA are know but also that the induction of the idiotypic network results in tumor therapy. See entire reference.

Hansen et al shows that CEA is a TAA (see entire reference). CEA is a well known tumor associated antigen that is expressed most adenocarcinomas of entodermally-derived digestive system epithelia, breast tumor cells and non-small cell lung cancer cells (see pages 1-2 of specification).

In view of the disclosure in Eshhar et al to use the chimeric genes in adoptive immunotherapy and in view of the disclosure of the WO which shows that such chimeric genes can be used in diseases caused by either tumors or infectious agents, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the chimeric genes of Eshhar et al in adoptive immunotherapy to treat tumors and infectious diseases. In view of the additional disclosure of Eshhar et al that many adoptive immunotherapy techniques lack specificity, it also would have been obvious to have the immunoglobulin encoding region of the chimeric gene encode an antibody that was specific for specific antigens on the surface of cells (ie TAA's). As demonstrated in Wagner et al, such antibodies are known in the art. Since it is within the purview of one skilled in the art two combine two known treatment techniques, it also would have been obvious to induce the idiotypic network (as described by Wagner et al) in combination with adoptive immunotherapy technique of Eshhar et al. In view of the well known knowledge that CEA is well known TAA, the use of CEA in the adoptive immunotherapy would have also been obvious to one or ordinary skill in the art.

Response to Applicant's arguments

Applicant argues that there is confusion in the art as to Class III anti-CEA antibodies and because of the confusion one skilled in the art would not be motived to select this. Hansen et al clearly analyzes this "confusion" and cites several antibodies with cross-react with MA and CEA and an antibody which is specific for CEA (antibody NP-4). The reference goes on to disclose that such specific antibodies are Class III and the reference goes on to make more Class III anti-CEA antibodies (see page 3479, first column). Thus, in view of Hansen there is no confusion.

Applicant argues that the reference do not teach the addition of cytokines. In the rejection, the Examiner relied on applicant's admission in the specification on page 22. In this section applicant admits that it is routine in the art to administer cytokines in immunotherapy to further the immune response. Thus, the additional use of cytokines is obvious to one of ordinary skill in the art.

New Grounds of Rejection

Claims 58 and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of hybridoma cell line producing MN-14 and W12. It is not clear that hybridomas possessing the identical properties of the afrementioned are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a cell line is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed hybridoma cell lines and monoclonal antibodies, this method will not necessarily reproduce antibodies and hybridomas which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive a monoclonal antibody and hybridoma identical to those claimed. Undue experimentation would be required to screen all of the possible antibody and hybridoma species to obtain the claimed antibodies and hybridomas.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed hybridomas, a suitable deposits for patent purposes, evidence of public availability of the claimed hybridomas or evidence of the reproducibility without undue experimentation of the claimed hybridomas, is required.

If the deposits are made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh